DEFENDANT EXHIBIT
CAH-WV-00564

Two-Person Approval Support Guidelines & Documentation
General Work Instructions

Scope

The general guidelines apply to all individuals who have the ability and/or direct responsibility for assessing and adjusting customer specific threshold limits as related to Oxycodone and Hydrocodone within the electronic monitoring system of Cardinal Health's Suspicious Order Monitoring (SOM) program.

Statement

Cardinal Health's Quality and Regulatory Affairs (QRA) department will have a process to increase threshold limits for higher volume customers for specific drug families.[1] These guidelines define the terms "higher volume customers" and "specific drug families"; outline the specific levels that require two-person concurrence, and outline the corresponding documentation required when making threshold limit adjustments that require two-person concurrence.

Cardinal Health has chosen to take a more conservative approach, requiring two-person concurrence to increase a threshold limit for Oxycodone or Hydrocodone for a retail or retail chain pharmacy above 20,010 dosage units. This more conservative approach is not required by the MOA, nor has Cardinal Health determined this is necessary to prevent diversion.

When required, two-person concurrence should be completed prior to making an increase to the threshold limit. Two-person concurrence is considered to be met upon completion of the following actions:

1. For threshold limit increases between 20,010 and 39,999, the requestor **and** Director of Analytics and Compliance, Director of Pharmacy Assessment, Director of Pharmacy Compliance, Director of Customer Analytics **or** Vice President of Supply Chain Integrity must review and approve the threshold limit increase.

2. For threshold limit increases 40,000 and above the requestor **and** Vice President of Supply Chain Integrity **or** Senior Vice President of Quality & Regulator Affairs or designee must review and approve the threshold limit increase.

3. The threshold limit increase is appropriately documented. Documentation should include the value the threshold limit was changed to, the name of the second level approver and date the second level approval was reviewed and approved.

    I. Threshold limit changes made within ADC are to be documented within the workflow functionality. The requestor should document the basis for the change and the proposed limit.

    II. Threshold limit changes made within Distrack or outside of ADC require the completion of Two-Person Approval Memo[2]. This document is to be retained as part of the customer's due diligence file within IBM Content Manager. The requestor is responsible for ensuring the appropriate documentation is completed.

Two-person concurrence is not required in the following scenarios:

- **Threshold Decreases**: Only threshold limit increases will require two-person concurrence. A reduction in a threshold limits does not require two-person concurrence.

[1] These guidelines specifically refer to Cardinal Health's Obligations outlined in the Memorandum of Agreement (MOA) with the Drug Enforcement Administration signed on May 14th, 2012.
[2] See Appendix 1 for the Two-Person Approval Memo template.

- **Ending and Single Digits**: Threshold limits increases completed solely to add an ending digit (coding mechanism) do not require two- person concurrence. Ending and single digits are added to indicate to the QRA team a specific message about the threshold limit

- **Sub-Base threshold settings**: A sub-base code threshold is a strength-specific threshold within a drug family. Sub-base code threshold limits are calculated based on a percentage of the drug family threshold limit. Specific percentages have been established for each active sub-base code. When two-person concurrence is granted for an increase in threshold limit, two-person concurrence is not needed for the sub-base code (unless deviating with an increase above the standard percentage calculation

- **LV-TAC**: Threshold limit increases approved by the LV-TAC (Large Volume-Tactical and Analytical Committee) do not require a separate two-person concurrence outside of the LV-TAC meeting. The two-person concurrence is embedded in the fact that multiple members of our leadership have approved these threshold limits.

- **Mass Uploads**: Threshold limit increases done through mass upload, to reset/meet the new objective and quantitative criteria (script count) outlined in the threshold limit setting methodology do not require a separate two-person concurrence. The two-person concurrence is embedded in the fact that multiple members of our leadership have approved these threshold limits.

- **Baseline Threshold Limits:** During the new account set-up process, baseline threshold limits are assigned to new Cardinal Health accounts. The baseline threshold limits are default values and may be increased or decreased depending on the customer. Baseline threshold limits that are mass loaded during the new account set-up process will not require two-person approval.

Appendix 1

Two-Person Approval

Memo

Cardinal Health
7000 Cardinal Place
Dublin, Ohio 43017
614-757-5000

CardinalHealth

Date: [MERGEFIELD Memo_Date * MERGEFORMAT]

To: File

From: [MERGEFIELD Author_Name * MERGEFORMAT]

Subject: [MERGEFIELD Pharmacy_Name * MERGEFORMAT] – DEA# [MERGEFIELD DEA_Number * MERGEFORMAT]

This customer was reviewed by [MERGEFIELD LV_TAC_Review_Date * MERGEFORMAT] and [MERGEFIELD LV_TAC_Review_Date * MERGEFORMAT] on [MERGEFIELD LV_TAC_Review_Date * MERGEFORMAT].

Based on the information available to QRA, the following new thresholds have been applied to this customer (please fill as 'none' if no changes have been made):

a. Oxycodone (9143): [MERGEFIELD Oxy_New_Threshold * MERGEFORMAT]

b. Hydrocodone (9193): [MERGEFIELD Hydro_New_Threshold * MERGEFORMAT]

Comments (if applicable)

[MERGEFIELD Comments * MERGEFORMAT]